Port system

The invention relates to a port system which is implanted to provide access to a remotely situated site of action to which an active substance is to make its way.

The port system has a subcutaneously implantable housing in which is arranged a chamber for receiving the active substance. The chamber in the port is closed off by a piercable membrane which is situated below the skin. For the injection of the active substance, the skin and the membrane are pierced by a needle and the active substance is injected into the chamber. From the chamber, the active substance then makes its way to the site of action via the catheter.

DE 41 29 782 C1 describes a port system which comprises a port and a catheter. The port has a housing which has an opening at the bottom to receive the active substance and an opening at the top to receive the membrane. The membrane is held in the opening by a clamping ring which exerts a pressure on the membrane, so that the membrane curves outwards. It is a disadvantage that the membrane is made difficult to fit. For an adhesive-bonded or welded connection, it is necessary for the clamping ring, which is under pressure, to be held in position. When for example the clamping ring is to be bonded on, it has to be held against the housing until such time as the adhesive has cured.

For the connection of the catheter, the known port has a tapering connecting piece which is in fluid connection with the central opening in the housing. The catheter is pushed onto the tapering connecting piece. The catheter is fixed to the connecting piece by means of a clamping sleeve which is screwed to the housing. A coupling of this kind for flexible lines is described in detail in DE 41 29 781 A1. It is a disadvantage that, once the clamping sleeve has been fitted, it cannot be seen how far the catheter has been pushed onto the tapering connecting piece. However, if it is not properly fitted, there is a risk of the flexible catheter coming loose from the connecting piece. It is also a disadvantage that, being a separate item, the clamping sleeve can easily be lost. This makes handling more difficult.

When an active substance is being injected with a needle, care has to be taken to see that the membrane situated beneath the skin is accurately targeted. If however the needle impacts not

on the membrane but on the housing, there is a danger that the needle will slip off the housing and will injure the catheter emerging from the housing.

The object underlying the invention is to provide a port for a catheter which can easily be assembled without any costly or complicated assembly work. The object of the invention is, in particular, to provide a port which allows the membrane to be fixed in place easily in the housing and which allows the catheter to be fixed easily to the connecting piece.

A further object of the invention is to provide a port for a catheter in which the risk of the catheter being injured when an active substance is being injected is reduced.

These objects are achieved, in accordance with the invention, by virtue of the features of claims 1, 15 and 29. Advantageous embodiments form the subject of the dependent claims.

The port according to the invention for a catheter has, for the fixing of the catheter to the connecting piece, two clamping jaws which are connected to the housing and which have clamping faces which are situated opposite one another. The clamping jaws can be moved from a first position, in which they are spaced away from the housing laterally, to a second position in which they fix the catheter in place between their clamping faces by a clamping action. The clamping jaws, when they are spaced away from the housing laterally, have the advantage that they do not obstruct the view when the catheter is being pushed onto the connecting piece. Hence the seating of the catheter on the connecting piece can be checked. It is also advantageous that the doctor is not obstructed by the clamping jaws when pushing on the catheter. To fix the catheter to the connecting piece, the clamping jaws merely need to be moved to the second position. Handling is simplified in this way.

In a preferred embodiment of the invention, the clamping jaws are fastened to the housing by fastening arms of a resilient form. It is advantageous on the one hand that the clamping jaws are securely fastened to the housing by the resilient fastening arms and on the other hand that the said jaws are easy to move. It is also advantageous that the resilient fastening arms do not make it necessary for complicated fastening techniques to be employed. Basically however, the clamping jaws may also be fastened to the housing by means of joints or sliders.

In a further preferred embodiment, the fastening arms form a clasp which fits round the sides of the housing and which is fastened to the housing at the opposite end from the connecting piece. This further simplifies the complicatedness of the structure. The fastening arms in the form of a clasp may be produced as a separate item, such as an injection moulding for example, and may be connected to the housing at a later stage. It is however equally possible for the clasp to be produced together with housing. The fastening of the clasp to the end of the housing opposite from the connecting piece makes it possible for the clamping jaws to have a relatively large range of movement. Consequently, the clamping jaws may be spaced a relatively long distance away from the housing laterally in the first position, thus creating a clear space which is as large as possible in the region of the connecting piece.

In a further preferred embodiment, provision is made for the clamping jaws to be locked to the housing by latching in the second position. Because the clamping jaws have a secure grip on the housing, it is ensured that the connection will not come loose.

The housing advantageously has lateral guide grooves in which the clamping jaws are guided. This ensures that, although the clamping jaws are able to be spaced away laterally, they do nevertheless have a sufficiently good grip on the housing.

For the clamping jaws to be secured to the housing by latching, steps are advantageously formed in the guide grooves, the clamping jaws having latching hooks. Additional fixing may be obtained by giving the clamping jaws spigots and holes which are associated with one another. When the clamping jaws are pressed together, the spigots engage in the holes, thus producing an interengaged connection.

Assembly of the port is further facilitated by virtue of the fact that the chamber is formed in an insert element which is locked in an opening in the housing, with the membrane interposed and clamped, in such a way that the insert element exerts an applying pressure on the membrane. The insert element thus not only forms the chamber for the active substance but also represents an assembling part by which the membrane is fixed in place under pressure. Once the membrane has been fixed in place, both the insert element and the membrane may be welded or adhesive-bonded to the housing. The crucial advantage is that the membrane can be preloaded without any additional clamping device.

In a preferred embodiment, the insert element and the housing form a bayonet connection. The bayonet connection enables the insert element to be locked easily but securely in the housing. Basically however, any other way of connecting the insert element and housing is also possible. The insert element may for example equally well be screwed to the housing.

The insert element advantageously has a projecting step and the opening in the housing has a groove having a lateral undercut, in which undercut the projecting step on the insert element seats when the latter is locked in the housing.

In a preferred embodiment, the insert element is securely held in the housing by virtue of the fact that the connecting piece is a canula which is inserted in mutually aligning holes in the housing and the insert element. The canula thus stops the insert element from twisting in the housing, and the projecting step is thus securely seated in the lateral undercut. It is also advantageous that the canula, insert element and housing are held in position with a slight clamping action when they are being adhesive-bonded.

A seal is preferably obtained by pressing adhesive into the gap between the insert element, membrane and housing. The adhesive may be injected into the groove in the housing. To simplify the bonding of the canula too, channels which start from the groove and run to the mutually aligning holes in the housing and the insert element may be provided in the wall of the insert element.

The undercut and the mutually aligning holes in the housing and the insert element are advantageously arranged diametrically opposite one another, which simplifies the removal of the workpieces from the mould at the time of manufacture.

The risk of the catheter being injured by the injection needle is avoided by providing a projecting step on the upper side of the port between the membrane and the connecting piece. If the injection needle impacts not on the membrane but on the housing, the projecting step stops the needle from slipping off the port and piercing the catheter.

In a preferred embodiment, the projecting step is formed on the clamping jaws which fit firmly round the catheter pushed onto the connecting piece. The clamping jaws thus serve not only to fix the catheter in place but also to protect it.

An embodiment of the invention is elucidated in detail below by reference to the drawings. In the drawings:

Fig. 1 is a view from above of one embodiment of the port, showing the clamping jaws, for fixing the catheter connected to the housing in place by clamping, resting against the housing;

Fig. 2 shows the port of Fig. 1 from below;

Fig. 3 is an exploded view of the port from below, with the clamping jaws spaced away from the housing;

Fig. 4 is an exploded view of the port from below from a different direction, with the clamping jaws spaced away;

Fig. 5 is a view of the port from above, with the clamping jaws spaced away, and

Fig. 6 is a section through the insert element having the chamber for receiving the active substance.

Fig. 1 is an enlarged view from above of the port-catheter, which comprises a port 1 and a catheter 38. The port 1, which may be approximately the size of a fingertip, has a shallow housing 2 which is implanted subcutaneously. The upper side, which lies under the skin, of the housing 1 is identified by reference numeral 3, its underside by reference numeral 4, its front end by reference numeral 5, its rear end by reference numeral 6 and its longitudinal sides by reference numerals 7 and 8. The longitudinal sides 7, 8 of the housing 1 run to the front end 5 of the housing at a shallow angle. The housing is thus shaped like a computer mouse.

The housing 2 may for example be produced from plastics material as an injection moulding. Basically however, it may equally well be composed of other compatible materials such as metal or ceramic material, for example. It has a central cylindrical opening 9 which is closed off by a circular piercable membrane (septum) 10. The membrane 10, which is inserted in

the opening and which is of a diameter which approximately corresponds to that of the opening, is supported against an abutment (not shown) which extends round at the top end of the opening. The upper side of the membrane 10 is exposed at the upper side of the housing, thus enabling it to be pierced by an injection needle.

A cylindrical insert element 11 is inserted in the central opening 9 in the housing as a good fit (Fig. 2). Formed in the insert element 11 is a cylindrical chamber 12 to receive the active substance to be administered (Fig. 6).

It is an advantage that the insert element 11 can be produced, independently of the housing 2, from different compatible materials such for example as plastics material or metal, and particularly titanium, or ceramic material, without the entire port having to be altered. This is an important consideration particularly when, for example, the insert element may come into contact with blood taken in via the catheter, because the different materials have different levels of acceptability with regard to compatibility with blood.

The insert element forms, with the housing 2, a bayonet connection. For this purpose, the insert element 11 has a projecting cylindrical step 12 and the opening 9 has a axial groove 13 in its wall into which the step 13 can be pushed as a good fit. To lock the step 12, the groove 13 has a lateral undercut 13 in which the step 12 engages on the insert element 11 being twisted (Fig. 4). The bayonet connection is so designed that the insert element 11 exerts an adequate applying pressure on the membrane 10 for the membrane 10 to curve outwards.

At the rear end 6, the housing 2 has a hole 15, which aligns with a hole 16 of the same diameter in the cylindrical wall of the insert element 11 when the insert element has been inserted in the housing and locked by twisting. The holes 15 and 16 in the housing and in the insert element 11 are situated diametrically opposite the undercut 14, the groove 13 being offset sideways for this purpose. Advantages for production arise from this arrangement at the time of removal from the mould.

Mounted in the mutually aligning holes 15, 16 in the insert element 11 and the housing 2 is a tubular canula 17 whose projecting end portion forms the connecting piece 18 of the port onto which the end portion of the catheter 38 is pushed. The end of the connecting piece 18 preferably tapers on the outside. The canula 17 which extends through the two holes 15, 16

not only creates a fluid connection between the chamber 12 and the connecting piece 18 but also as it were acts to secure the insert element against twisting. This has the following advantages at the time of assembly.

For assembly, the insert element 11 is inserted and locked in the opening 9 in the housing. Thus can be done with a suitable tool which has projections which engages in holes 40 in the insert element 11. The canula 17 is then pushed into the hole 15, 16. Adhesive is now pressed into the groove 13 and distributes itself evenly via circular channels (not shown) which are provided in the wall of the opening 9 in the housing, thus causing the adhesive to completely fill the gap between the insert element 11, membrane 10, canula 17 and housing 1. The insert element, the membrane and the canula are thus sealed to the housing. Additional clamping devices and the like are not required during the curing of the adhesive because the insert element inserted in the opening 9 is fixed in place by means of the bayonet connection and the canula 7.

To fix the catheter 38 which is pushed onto the connecting piece 18 in place by clamping, the port has two clamping jaws 19, 20 which have respective clamping faces 21, 22 corresponding to the diameter of the canula. The two clamping jaws 19, 20 are movable between a first position, which is shown in Figs. 3 to 5, and a second position (Figs. 1 and 2). In the second position, the clamping jaws fit firmly round the catheter 38 so that the catheter is securely mounted on the connecting piece 18. In the first position on the other hand, the clamping jaws 19, 20 are spaced away from the housing laterally so that on the one hand there is enough free space for the catheter to be pushed onto the connecting piece and on the other hand a visual check can be made on the catheter when pushed onto the connecting piece.

The clamping jaws 19, 20 are fastened to the housing 1 by respective fastening arms 27, 28 of a resilient form. The fastening arms 27, 28 form a U-shaped clasp 29 which is seated in guide grooves 30 extending at the front end 5 and along the longitudinal sides 7, 8 of the housing 1. By its arcuate central portion 31, the clasp 29 is fastened only to the front end 5 of the housing, thus allowing the lateral portions of the clasp to splay outwards.

On their insides, the clamping jaws 19, 20 have respective latching hooks 32, 33 which slide in the guide grooves 30 when the fastening arms 27, 28 splay apart. The guide grooves 30 are each in two parts, of which one part 30a extends along the longitudinal side 7, 8 of the

housing and the other part 30b extends along the rear end 6 of the housing. In the region of the transition between the two parts 30a, 30b, the guide grooves 30 form projecting steps 34, 35. In the first position, in which the clamping jaws 19, 20 are spaced away laterally, the inner faces of the latching hooks, 32, 33 are supported against the steps 34, 35.

In the parts 30b of the guide grooves 30 at the rear end 6 of the housing, there are formed respective steps 36, 37 against which the latching hooks 32, 33 are supported when the clamping jaws 19, 20 are in the second position in which they fix the catheter in place by clamping. Provided in the end face 23 of one clamping jaw 19 are holes 24, in which spigots 25 which are provided on the end face 26 of the other clamping jaw 20 engage. Clamping ridges 40, 41 are also provided on the clamping faces 21, 22.

The outline of the clasp 30 and the outline of the clamping jaws 19, 20 having the latching hooks 32, 33 match the outline of the guide grooves 30 and the outline of the housing, which means that the clasp and the claming jaws and the housing fit together well. Provided in the front end 5 of the housing and in the clamping jaws are fixing holes for fabric to allow the port system to be sewn on.

Provided on the upper side of the clamping jaws 19, 20 between the membrane 10 and the connecting piece 18 is a projecting step 39 which stops an injection needle which impacts on the housing from slipping off the housing and injuring the catheter. The projection step 39 is in two parts 39a, 39b, each of which extends across the upper side of the relevant clamping jaw substantially perpendicularly to the longitudinal axis of the connecting piece 18.

If the injection needle impacts on the upper sided of the housing 2 of the port 1 between the membrane and the connecting piece 18, the needle might slip off in the direction of the connecting piece 18 and perforate the flexible catheter tube. This would make it necessary for the port system to be replaced, which is a surgically complicated business. If the perforation is not detected, there is also a risk of the active substance not making its way to the site of action or not doing so in sufficient quantity. The active substance may also emerge at the wrong site of action, i.e. at the perforation. The projecting step 39 is able to prevent this because the injection needle impacts on the housing with a certain amount of force, and if it slips off in the direction of the connecting piece 18 it will be diverted sideways by the step 39 substantially perpendicularly to the connecting piece.